United States District Court
District of Massachusetts

AMPHASTAR PHARMACEUTICALS, INC. and INTERNATIONAL MEDICATION SYSTEMS, LTD.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 16-10112-NMG**
MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This is an antitrust case in which plaintiffs Amphastar Pharmaceuticals, Inc. ("Amphastar Pharmaceuticals") and International Medication Systems, Ltd. ("IMS")(collectively, "Amphastar" or "plaintiffs") allege that defendants Momenta Pharmaceuticals, Inc. ("Momenta Pharmaceuticals") and Sandoz Inc. ("Sandoz")(collectively, "Momenta" or "defendants") restricted trade and prevented competition in the manufacture and sales of the generic drug enoxaparin.

Pending before the Court is Momenta's motion to dismiss the complaint (Docket No. 17), which will be treated as a motion to dismiss the amended complaint pursuant to the parties' stipulation. For the following reasons, the motion to dismiss will be denied.

I. Background and Procedural History

A. The Parties

Plaintiff Amphastar Pharmaceuticals is a pharmaceutical company located in California which develops, manufactures and sells pharmaceutical products including generic enoxaparin throughout the United States. Enoxaparin is an anti-coagulant used to prevent blood clots.

Plaintiff IMS is a wholly-owned subsidiary of Amphastar Pharmaceuticals with a principal place of business in California. It manufactures the active pharmaceutical ingredient in Amphastar's generic enoxaparin.

Defendant Momenta Pharmaceuticals is the assignee of United States Patent No. 7,575,886 ("the '886 patent") which concerns a testing process used in manufacturing enoxaparin. Momenta Pharmaceuticals acts as the contract laboratory for defendant Sandoz and is a Delaware corporation with its principal place of business in Massachusetts.

Defendant Sandoz distributes, markets and sells generic enoxaparin products throughout the United States. It is a Colorado corporation with its principal place of business in New Jersey. It allegedly entered into a profit-sharing, contractual relationship with Momenta which rendered it the exclusive licensee of the '886 patent.

B. The Alleged Conduct

In November, 2003, defendants entered into a Collaboration and License Agreement ("Collaboration Agreement") to develop, market and sell "enoxaparin sodium injection" in the United States. The Collaboration Agreement granted an exclusive license of the '886 patent, which had not yet issued, to Sandoz. Plaintiffs claim that the agreement "heavily" incentivized anti-competitive behavior by requiring Sandoz to make "milestone payments", profit sharing payments and royalty payments to Momenta Pharmaceuticals for the privilege of remaining the sole source of generic enoxaparin in the United States.

In or before February, 2007, the United States Pharmacopeial Convention ("USP") commenced the process for establishing a drug standard to test enoxaparin products. The USP is a scientific and impartial nonprofit organization which sets uniform standards for the identity, strength, quality and purity of medicines, food ingredients and dietary supplements. USP policy prohibits it from favoring one manufacturer over another during the standard-setting process and requires its committee members to disclose any conflicts of interest. A member with a conflict cannot attend the final discussion, deliberation or vote on the conflicted issues.

Sanofi-Aventis (“Aventis”) proposed the standard known as USP Method <207> (“the 207 Method”) to the USP. Dr. Zachary Shriver (“Dr. Shriver”), an employee and director of Momenta Pharmaceuticals who would later be named as an inventor on the ‘886 patent, served as Momenta’s representative on the USP panel tasked with developing and approving the USP standard for enoxaparin. Sandoz also participated in the panel discussions.

The amended complaint alleges that Dr. Shriver and defendants learned, during the USP’s consideration of the 207 Method, that Aventis had a pending patent application containing claims which would read on the 207 Method. Defendants purportedly demanded that Aventis abandon its patent application so that any member of the public could practice the enoxaparin standard adopted by the USP. Plaintiffs proffer that demand as evidence that defendants were “very familiar” with the 207 Method and the USP policy on conflicts of interest.

In November, 2008, the USP convened a panel meeting which commenced with a review of the USP policy on conflicts. Momenta Pharmaceuticals presented the 207 Method in a “detailed” presentation to the USP. USP staff reported that it was “not aware of any patent issue that may cover the test”. Plaintiffs allege that neither Dr. Shriver, who was present at the meeting, nor any other representative of the defendants disclosed to the USP the conflicts posed by their own pending application for the

‘886 patent and the Collaboration Agreement. Plaintiffs assert that no other USP panel member knew that the ‘886 patent, which eventually issued in August, 2009, would cover the use of the 207 Method.

In December, 2009, the USP approved and adopted the 207 Method as its enoxaparin standard after Aventis agreed to abandon its patent application. The USP convened two more panel meetings in March and April of 2011. Plaintiffs claim that Dr. Shriver and another Momenta representative participated in the meetings and continued to violate their duty to disclose their and the defendants’ conflicts of interest to the USP.

Sandoz was the first entity to receive approval from the United States Food and Drug Administration (“FDA”) to sell generic enoxaparin in the United States in July, 2010. Defendants thus became the sole source of generic enoxaparin until Amphastar also received FDA approval to sell enoxaparin September, 2011. Plaintiffs allege that 1) the FDA required them to comply with the 207 Method as a condition of approval, 2) the 207 Method included steps protected by the patented method, 3) the ‘886 patent excluded unlicensed competitors from receiving FDA approval and thus 4) the ‘886 patent excluded new entrants from the market.

Two days after Amphastar received FDA approval, Momenta commenced an action in this Court alleging that Amphastar

infringed the ‘886 patent. Amphastar claims that the lawsuit prevented it from selling generic enoxaparin in the relevant market.

C. Procedural History

Amphastar initiated this antitrust action by filing a complaint in the Central District of California in September, 2015. The complaint alleges violations of 1) federal antitrust law, i.e., the Sherman Act, 2) California antitrust law, i.e., the Cartwright Act and 3) California state law on unfair business practices. Amphastar amended the complaint in December, 2015 to replace “Sandoz, Pharmaceuticals, Inc.” with “Sandoz Inc.” as a named defendant.

The amended complaint asserts that Momenta engaged in anti-competitive conduct by executing the Collaboration Agreement, failing to disclose conflicts to the USP and commencing a patent infringement suit against Amphastar for using the 207 Method selected by the USP and required by the FDA. The amended complaint alleges that the anti-competitive conduct kept the price of generic enoxaparin artificially high which, in turn, cost consumers “billions of dollars in overcharges”.

Under Amphastar’s theory of antitrust liability, 1) the relevant product market is defined as the United States market for generic enoxaparin or, alternatively, enoxaparin, 2) generic entry into the market results in substantial reductions in

price, 3) price-sensitive consumers of generic enoxaparin treat different brands of generic enoxaparin as reasonable substitutes and 4) generic manufacturers consider the prices set by other generic manufacturers as directly affecting their own prices.

In December, 2015, Momenta filed a motion to dismiss this action and a separate motion to transfer it from the Central District of California to the District of Massachusetts based upon the "substantial overlap" of issues, claims, witnesses and evidence between the instant case and the prior patent case pending in this Court. The California court allowed the motion to transfer. The case was transferred to the District of Massachusetts and assigned to this Session in January, 2016 but Amphastar filed a writ of mandamus to the Ninth Circuit Court of Appeals ("the Ninth Circuit") to appeal that transfer on personal jurisdictional grounds. That petition was denied in May, 2016.

In July, 2016, this Court allowed Momenta's motion to dismiss, reasoning that Amphastar's claims were precluded by the Noerr-Pennington doctrine. Amphastar appealed that order to the First Circuit Court of Appeals which reversed and remanded the case in March, 2017, directing this Court to consider defendants' alternative arguments for dismissal. The parties submitted supplemental memoranda in that regard in April and May, 2017.

II. Momenta's Motion to Dismiss

A. Legal Standard

To survive a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a complaint must contain "sufficient factual matter" to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 667 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011). A court may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Id. Rather, the relevant inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw. Id. at 13.

When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to judicial notice. Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011).

B. Sherman Act Violations

Amphastar alleges that defendants violated the Sherman Act by (1) entering into an agreement in restraint of trade which blocked it from selling generic enoxaparin and (2) wrongfully acquiring monopoly power by deceiving the USP into adopting a standard which they later claimed was covered by defendants' patent. Defendants respond that Amphastar has failed to plead facts establishing that their conduct caused Amphastar's injury. Furthermore, defendants suggest that Amphastar does not sufficiently allege a restraint of trade because (1) the 207 Method is not mandatory and (2) there are no plausible allegations that Momenta intended to induce the USP into approving the 207 Method.

1. Causation

First, defendants contend that the Amphastar has failed to plead facts sufficient to demonstrate that it suffered an antitrust injury as a result of defendants' conduct. They claim that Amphastar has not adequately alleged a causal connection between the USP proceedings and Amphastar's decision to adopt the 207 Method because Amphastar first filed its Abbreviated New Drug Application ("ANDA") in 2003 in which it was required to describe the quality control procedures it would use to confirm that its generic enoxaparin had the appropriate structural characteristics. Defendants note that Amphastar adopted the 207

Method before it was approved by the USP and did not amend its ANDA after the USP approved the 207 Method.

Amphastar emphasizes in its response that, although it submitted the ANDA in 2003, that initial application was "inconsequential" because the FDA did not approve the application until 2011. In the intervening years between the application and the approval, the USP adopted the 207 Method. As a result of that adoption, Amphastar suggests, the FDA conditioned its 2011 approval on Amphastar's compliance with the 207 Method. By contrast, had the USP not adopted Method 207, Amphastar would not have been required to comply with it for FDA approval and defendants would not have had the market power to exclude Amphastar.

A plaintiff in an antitrust case must demonstrate that there is a causal connection between the defendant's illegal practice and the antitrust injury. Sullivan v. Nat'l Football League, 34 F.3d 1091, 1103 (1st Cir. 1994). A plaintiff need not prove that the antitrust violation was the "sole cause of their injury, but only that it was a material cause". Id. (citing Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 13 (1st Cir. 1979)). An antitrust violation can constitute a material cause even where an injury has additional independent causes. See e.g., In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231 (D. Mass. 2014) (internal citation omitted)

(noting that the material cause condition has been interpreted as a proximate cause requirement). The First Circuit has noted that causation questions are "peculiarly within the competence of the factfinder" and should be left for the jury. Peckham v. Cont'l Cas. Ins. Co., 895 F.2d 830, 837 (1st Cir. 1990) ("Causation questions of this sort are normally grist for the jury's mill.").

Amphastar has sufficiently alleged that defendants' actions before the USP while that organization was considering the proposed standards for enoxaparin were a material cause of Amphastar's antitrust injury. Momenta's focus on the ANDA is misplaced. While defendants suggest that Amphastar must allege facts supporting an inference that Amphastar adopted the accused procedures as a result of the USP proceedings, the alleged antitrust injury need not have been caused by Amphastar's adoption of the 207 Method but rather by the FDA's approval made contingent on Amphastar's adoption of the USP's official test method to test for its enoxaparin.

Amphastar alleges that Momenta's deceptive conduct in front of the USP led to the approval of the 207 Method and the subsequent exclusion of Amphastar from the marketplace. The adoption of the 207 Method by the USP made the FDA's approval of the sale of enoxaparin by Amphastar conditional on its use of an infringing procedure. Accordingly, Amphastar has adequately

pled that the defendants' conduct at the USP was a material cause of the antitrust injury.

2. Restraint of Trade

Defendants contend that Amphastar fails to allege a restraint of trade sufficient to support an antitrust claim because the 207 Method is not mandatory and defendants do not demonstrate that Momenta intentionally deceived the USP. According to defendants, while all manufacturers of generic enoxaparin must use a process that assures that the drug has the structural characteristics in the Enoxaparin Monograph, the 207 Method was not included in that monograph and was therefore not mandatory. Defendants request that the Court take judicial notice of eight documents that purportedly show that the method was not mandatory.

As a preliminary matter, Amphastar quibbles with the introduction of extrinsic documents and contends that the Court cannot take judicial notice of the documents for the purpose of establishing the truth of the statements therein. As the Court stated in its July, 2016 Memorandum and Order in this case, it construes defendants' request as pertaining to the existence of the documents and the statements therein but not to acceptance of the truth of such statements.[1] The Court will take judicial

[1] The First Circuit Court of Appeals did not address in its opinion this Court's ruling on defendants' request to take

notice of the existence of the documents identified by defendants. See e.g., Torrens v. Lockheed Martin Servs. Grp., Inc., 396 F.3d 468, 473 (1st Cir. 2005) (taking judicial notice of the existence of a document but not for the truth of the statements made therein).

> Section 2 of the Sherman Act makes it illegal to
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> monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations.

15 U.S.C. § 2. To state a monopolization claim under § 2, a plaintiff must adequately allege that defendant (1) has monopoly power in the relevant market and (2) has engaged in illicit "exclusionary practices" with "the design or effect of protecting or enhancing its monopoly position". Sterling Merch., Inc. v. Nestle, S.A., 656 F.3d 112, 125 (1st Cir. 2011) (quoting Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 195 (1st Cir. 1996) (internal citation omitted)).

Amphastar has articulated a cognizable claim that defendants wrongfully acquired monopoly power by deceiving the USP into adopting the 207 Method that defendants later asserted was covered by the '886 patent. The complaint contains allegations establishing that the USP adopts standards that are

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judicial notice. Amphastar Pharm., Inc. v. Momenta Pharm., Inc., 850 F.3d 52 (1st Cir. 2017).

enforced by the FDA and plausibly alleges that the 207 Method is mandatory.

While defendants contend that the USP and the FDA made clear that some unspecified alternative to the 207 Method would be permitted, there remain fact-intensive questions about the feasibility, availability and even existence of such alternatives. See e.g., Hosp. Auth. of Metro. Gov't of Nashville v. Momenta Pharm., Inc., 244 F. Supp. 3d 705, 716 (M.D. Tenn. 2017) (finding that "the effect of the testing requirement on the market for enoxaparin depends on the relative feasibility of those other tests [and] the likelihood that they would be considered adequate alternatives to Method <207> under the USP standards"). Amphastar has plausibly alleged that it was required to use the 207 Method to obtain and maintain its generic enoxaparin approval from the FDA. The existence of alternatives is a factual question inappropriate for resolution on a motion to dismiss.

Defendants also suggest that Amphastar has failed to state an antitrust claim because Momenta opposed the adoption of the 207 Method and, therefore, Amphastar cannot demonstrate that Momenta intentionally deceived the USP. In the complaint, Amphastar alleges that defendants intentionally failed to disclose the '886 patent to the USP thereby contravening the conflict rules put in place by the USP. Those allegations are

sufficient, if proven, to establish that defendants misrepresented their interest at the USP in order to secure market power.

Intentional misrepresentations designed to deceive a standard-setting organization can constitute an antitrust violation. See Broadcom Corp. v. Qualcomm, Inc., 501 F.3d 297, 314 (3d Cir. 2007). The Third Circuit Court of Appeals outlined the contours of such a violation, holding that

> [d]eception in a consensus-driven private standard-setting environment harms the competitive process by obscuring the costs of including proprietary technology in a standard and increasing the likelihood that patent rights will confer monopoly power on the patent holder.

Id. By incorporating patented technology into a standard, the patent-holder obtains market power because adoption of the standard eliminates alternatives to the patented techonolgy. Id. (citing Am. Society of Mech. Eng'rs, Inc. v. Hydrolevel Corp., 456 U.S. 556, 559 (1982)). Amphastar has alleged facts sufficient to support its claim that Momenta intentionally deceived the USP to obtain market power.

C. Compulsory Counterclaim

Momenta contends that Amphastar's antitrust claims are compulsory counterclaims that Amphastar was required to raise in the patent infringement suit between the parties, Momenta Pharm., Inc. et al. v. Amphastar Pharm., Inc. et al., 11-cv-11681 (D. Mass.) ("the patent case"). Momenta suggests that

because Amphastar's antitrust claims are predicated on Momenta's assertion of the '886 patent and its prosecution of the patent case, Amphastar was required to raise them in that action.

Under Fed. R. Civ. P. 13,

> [a] pleading must state as a counterclaim any claim that—at the time of its service—the pleader has against an opposing party if the claim: (A) arises out of the transaction or occurrence that is the subject matter of the opposing party's claim; and (B) does not require adding another party over whom the court cannot acquire jurisdiction.

Fed. R. Civ. P. 13(a). In Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 671 (1944), the Supreme Court held that a claim for antitrust damages was a permissive, rather than a compulsory, counterclaim to a prior claim of patent infringement. The Court determined that although the antitrust claim could have been asserted in the patent suit under Fed. R. Civ. P. 13(b), it did not follow "that the failure to do so renders the prior judgment res judicata as respects it". Id. The First Circuit, applying Mercoid, has held that

> a counterclaim for treble damages is permissible in nature so that failure by a defendant to plead it in a prior patent suit does not bar a subsequent independent suit by him under the anti-trust laws.

Fowler v. Sponge Prods. Corp., 246 F.2d 223, 227 (1st Cir. 1957).

Momenta urges this Court to limit Mercoid to its facts and adopt methods of distinguishing its holding endorsed by two other circuit courts. The Second Circuit Court of Appeals has

drawn a distinction between antitrust claims that rely on misuse of a valid patent as opposed to antitrust claims based on patent invalidity. Critical-Vac Filtration Corp. v. Minuteman Intern., Inc., 233 F.3d 697, 703 (2d Cir. 2000). Because invalidity defenses in patent cases are generally related to the underlying patent infringement claims, the Court determined that the Mercoid exception to Fed. R. Civ. 13(a) did not apply because Mercoid involved an antitrust claim based on misuse of a valid patent. Id. at 703-04.

Amphastar's antitrust claims do not implicate the validity of the '886 patent. Instead, Amphastar claims that defendants conspired to deceive the USP and relies on a theory of misuse of a valid patent. Momenta's insistence that the patent misuse/patent validity distinction applies is, therefore, tenuous. But cf. Eon Labs., Inc. v. Smithkline Beecham Corp., 298 F. Supp. 2d 175, 181 (D. Mass. 2003) (finding that where an antitrust claim was based on patent invalidity the patent misuse/patent validity distinction from Critial-Vac applied). Although Momenta is correct that the facts underlying Amphastar's equitable defenses in the patent case are entwined in the antitrust claims in this case, the Court is bound by Fowler and, accordingly, the patent case does not bar a subsequent independent suit under the antitrust laws. Fowler, 246 F.2d at 227.

D. Conspiracy

Defendants contend that Counts 1 and 3 of the complaint must be dismissed because Amphastar fails to plead facts supporting a plausible inference that Sandoz joined an antitrust conspiracy. Instead, defendants suggest, Amphastar makes a conclusory statement that Sandoz entered into a collaboration agreement with Momenta and acted in concert during the USP proceedings. Amphastar responds by stressing that the complaint sufficiently alleges an unlawful conspiracy by describing the terms of a collaboration and license agreement which would provide financial incentive for defendants to remain the sole providers of generic enoxaparin in the market.

Section 1 of the Sherman Act prohibits, in relevant part, "contract[s], combination[s] in the form of trust or otherwise, or conspirac[ies] in restraint of trade or commerce". 15 U.S.C. § 1. To state a claim under Section 1, an antitrust plaintiff must present either direct or circumstantial evidence of defendants' "conscious commitment to a common scheme designed to achieve an unlawful objective". Evergreen Partnering Grp., Inc. v. Pactiv Corp., 720 F.3d 33, 43 (1st Cir. 2013) (citing Monsanto Co. v. Spray-Rite Serv. Corp., 465 U.S. 752, 764 (1984)).

Amphastar plausibly alleges that the collaboration agreement between Sandoz and Momenta created financial

incentives for the companies to exclude other producers of generic enoxaparin from the marketplace. It purportedly documented specific milestone payments for maintaining their status as the sole providers and Sandoz's participation in the USP meetings concerning the 207 Method. See e.g., Coalition for ICANN Transparency, Inc. v. VeriSign, Inc., 611 F.3d 495, 503 (9th Cir. 2010) (finding that the plaintiff adequately pled the existence of a conspiracy by demonstrating that defendant had the intent to restrain trade by entering into a contract). Accordingly, Amphastar has alleged facts sufficient to support their claims under Section 1 of the Sherman Act.

ORDER

For the foregoing reasons, defendants' motion to dismiss (Docket No. 17) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton_____
Nathaniel M. Gorton
United States District Judge

Dated March 19, 2018